K140354

MAY 09 2014

2.0 510(k) Summary

Abbott RealTi*m*e CT/NG assay and an ancillary kit called the Abbott *m*ulti-Collect Specimen Collection Kit

Submitted By:

Abbott Molecular Inc.
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Trade Name: Abbott RealTi*m*e CT/NG (List No. 8L07-91) and
Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12)

Common Name: In vitro polymerase chain reaction (PCR) assay for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* and

Microbiological Specimen Collection and Transport Device

Classification Name: DNA-Reagents, Chlamydia
DNA-Reagents, Neisseria

Classification Code: Product Code: LSL, MKZ
Regulation Number: 866.3390 (Neisseria), 866.3120 (Chlamydia)
Device Class: 2 (Neisseria), 1 (Chlamydia)

Product Code: LIO
Regulation Number: 866.2900
(Microbiological specimen collection and transport device)
Device Class: 1 (Specimen Collection)

Predicate Device: Abbott RealTi*m*e CT/NG (List No. 8L07)

Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12)

2.1 Date of Preparation

May 8, 2014.

2.2 Purpose of the Submission

Abbott Molecular Inc is submitting this Traditional 510(k): Device Modification to inform FDA of a supplier change for the swab fiber component of the Abbott *m*ulti-Collect Specimen Collection Kit Swab Collection Device 655 (CD655) previously cleared as a component of Premarket Notification (K092704).

2.3 Manufacturer:

Abbott Molecular Inc. is the legal manufacturer of the Abbott RealTi*m*e CT/NG assay and the Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12).

Name:	Timothy Zurow, PhD
Title:	Director of Manufacturing Operations
Telephone	(224) 361-7379
Fax:	(847) 775-6777
Email:	timothy.zurow@abbott.com
Address:	Abbott Molecular Inc. 1300 E. Touhy Avenue Des Plaines, IL 60018

Establishment Registration No.: 3005248192

The Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12) is manufactured and assembled at the MML Diagnostic Packaging, Inc. facility indicated below:

Name:	Dale Pestes
Title:	Director Manufacturing Operations
Telephone:	(503) 666-8398
Fax:	(503) 666-8510
Email:	njndale@aol.com

MML Diagnostic Packaging, Inc.
1625 NW Sundial Road
PO Box 458
Troutdale, OR 97060

Establishment Registration No.: 3018348

2.4 Intended Use

The Abbott RealTi*m*e CT/NG assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae*. The assay may be used to test the following specimens from symptomatic individuals: female endocervical swab, clinician-collected vaginal swab, and patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected vaginal swab and patient-collected vaginal swab specimens; female and male urine specimens.

The Abbott *m*ulti-Collect Specimen Collection Kit is intended for the collection and transportation of male and female swab and urine specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrheae* per instructions provided. Refer to the specimen collection procedure in the package insert for specimen collection instructions for specific sample types.

Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Abbott *m*ulti-Collect Specimen Collection Kit is not intended for home use.

2.5 Device Description

The Abbott *m*ulti-Collect Specimen Collection Kit can be used to collect either a swab or a urine specimen. Each Abbott *m*ulti -Collect Specimen Collection Kit contains:

- One capped Transport Tube containing 1.2 mL Specimen Transport Buffer
- One Individually Packaged Sterile Specimen Collection Swab
- One disposable transfer pipette.

The Specimen Transport Buffer is used to stabilize DNA until sample preparation. The individually packaged sterile Specimen Collection Swab is used for swab sample collection and placed directly into the Transport Tube. The transfer pipette is used to add

approximately 3 mL of urine to the Transport Tube. The Abbott *m*ulti -Collect Specimen Collection Kit is for single use only.

The Abbott *m*ulti-Collect Specimen Collection Kit Swab is approximately 14 cm in length with a polyester fiber tip. The swab shaft has a polystyrene solid core that is orange in color. The swab has a molded score completely around the shaft, between 7.86 cm and 7.89 cm from the swab tip, to provide a clean break-point. The polyester-fiber swab tip is approximately 1.3 cm in length and less than 3.28 mm in diameter.

2.6 Comparison with Predicate Device

The proposed Abbott *m*ulti-Collect Specimen Collection Kit Swab (SW265) has the same intended use for the collection and transportation of clinical specimens for the direct, qualitative detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) as the current on-market Specimen Collection Kit Swab (SW260).

The primary function, component composition and technological characteristics of the proposed Abbott *m*ulti-Collect Specimen Collection Kit Swab is substantially equivalent to the current on-market device. The modification proposed does not affect the manufacturing facility location, manufacturing process and quality control procedures, the principle of operation, clinical data, patient population, final release testing of the product, indications for use or product labeling.

The similarities and differences between the proposed Abbott *m*ulti-Collect Specimen Collection Kit Swab and the current on-market device are shown in Tables 1 and 2. The differences are shown in *underlined italics* in the tables.

Table 1. Similarities and *Differences* between Current and Proposed Abbott *m*ulti-Collect Specimen Collection Swab

Feature	Current Swab (SW260)	Proposed Swab (SW265)
Intended Use	The Abbott *m*ulti-Collect Specimen Collection Kit Swab is intended for the collection and transportation of male urethral, female endocervical, clinician-collected or self-collected vaginal swab specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from symptomatic and asymptomatic individuals. For use with the Abbott RealTi*m*e CT/NG Assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae.*	Same
Where Used	Hospital, Clinical Physician Office	Same
Sample Types	Endocervical swab specimens	Same
	Self-collected vaginal swab specimens	Same
	Clinician-collected vaginal swab specimens	Same
	Male urethral swab specimens	Same

Table 2. Similarities and *Differences* between Current and Proposed Abbott multi-Collect Specimen Collection Swab

Feature	Current Swab (SW260)	Proposed Swab (SW265)
Manufacturing Facility	MML Diagnostics Packaging, Inc. Production Procedures Quality Control Procedures	Same
Design	Individually Packaged Sterile Specimen Collection Swab	Same
Swab Fiber Supplier	Dupont	*William Barnet and Sons, LLC*
Swab Bud Tip	DuPont Dacron	*Barnet P-2182*
Swab Fiber Tip Material	Polymer Polyester	Same
Swab Shaft	Polystyrene Solid Core	Same
Storage Conditions		
Unopened Kit	Stored at room temperature	Same
Specimen Transport	Stored at 2 to 30°C for up to 14-days after collection	Same
Long-term Storage	Store at -10°C or colder for up to 90-days after collection	Same

2.7 Summary of Studies

Biocompatibility

Biocompatibility of the Specimen Collection Kit Swab manufactured with the proposed polyester fiber was confirmed through cytotoxicity, irritation to skin and mucosal surfaces, and sensitization tests based on the No. G95-1 Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing guidance document.

90-Day Specimen Stability

The stability of deoxyribonucleic acid (DNA) of a sample in the Specimen Collection Transport Tube while in the presence of the proposed swab was determined by testing simulated high and low positive swab specimens stored at 2 to 8°C and at 30°C for 14 days or longer, followed by storage at -10°C or colder for 90 Days or longer.

The stability study for the Abbott *m*ulti-Collect Specimen Collection Kit swab is on-going. The intermediate data supports specimen storage at 2 to 30°C for 14 days and at -10°C or colder for 56 days.

Sample Freeze Thaw Stability

The stability of the DNA of a sample in the Specimen Collection Transport Tube while in the presence of the proposed swab was determined by testing simulated high and low positive swab specimens. Following five freeze-thaw cycles, the percent positive rate for 90 CT analyte samples and for 90 NG analyte samples was 100% (90/90) in the Abbott RealTi*m*e CT/NG assay.

LOD Confirmation

The collection and transfer of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) target analyte from the proposed Specimen Collection Swabs to Abbott *m*ulti-Collect Specimen Collection Transport Tubes Transport Buffer was determined by testing simulated low positive swab specimens.

The detection rate of 320 copies/400 µL of CT DNA was 100% (234/234) in the Abbott RealTi*me* CT/NG assay and the lower bound of the 95% one-sided confidence interval detection rate was 99%. The detection rate of 320 copies/400 µL of NG DNA was 98% (229/234) in the Abbott RealTi*me* CT/NG assay and the lower bound of the 95% one-sided confidence interval detection rate was 96%.

Reproducibility

A reproducibility study was performed testing a four-member panel of simulated swab specimens consisting of three different analyte concentrations of CT and NG. Swab specimens from 3 separate Swab lots were prepared and tested. The targeted concentration for CT ranged from 0 to 45,000 copies in each 400 µL sample input volume and for NG from 0 to 22,000 copies in each 400 µL sample input volume.

Seven replicates of each panel member were tested in each run. Nine runs were performed across 3 *m*2000 instrument systems for a total of 189 replicates tested of each panel member.

For each panel member and for each analyte (CT or NG), percent reproducibility was calculated overall (all instruments and swab lots combined), by instrument (across swab lots), and by instrument and swab lot.

The percent positive rate for the positive panel members and percent negative rate for the negative panel were greater than or equal to 99% for each analyte in the Abbott RealTi*me* CT/NG assay.

Accelerated Stressed Swab Stability

The stability of the DNA of a sample in the Specimen Collection Transport Tube while in the presence of swabs which were subjected to accelerated stress was determined by testing simulated low positive swab specimens containing a target concentration of 320 copies of CT and 320 copies of NG in each 400 µL sample preparation input volume.

The detection rate of the CT analyte was 100% and the lower bound of the 95% one-sided confidence interval detection rate was 96% for all conditions tested in the Abbott

RealTi*m*e CT/NG assay. The detection rate of the NG analyte ranged from 98 to 100% and the lower bound of the 95% one-sided confidence interval detection rate ranged from 93 to 96% for all conditions tested in the Abbott RealTi*m*e CT/NG assay.

Abbott *m*ulti-Collect Specimen Collection Kit Real-time Stability

The stability study for the Abbott *m*ulti-Collect Specimen Collection Kit Stability which includes the proposed swab is on-going and scheduled to be completed in December of 2015.

2.8 Conclusion Drawn from Studies

The submitted material in this premarket notification supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 9, 2014

Abbott Molecular Inc.
Stacy Ferguson
Senior Regulatory Affairs Specialist
1300 E. Touhy Avenue
Des Plaines, IL 60018

Re: K140354
Trade/Device Name: Abbott Real *Time* CT/NG Assay and Abbott *m*ulti-Collect Specimen Collection Kit
Regulation Number: 21 CFR 866.3390
Regulation Name: Neisseria spp. direct serological test reagents
Regulatory Class: II
Product Code: LSL, MKZ, LIO
Dated: February 10, 2014
Received: February 12, 2014

Dear Ms. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tamara V. Feldblyum -S for

Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K140354

Device Name: Abbott RealTi*m*e CT/NG Assay and
Abbott *m*ulti-Collect Specimen Collection Kit

Indications for Use:

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Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Abbott *m*ulti-Collect Specimen Collection Kit is not intended for home use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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